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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,965

03/25/2004

Dave S.B. Hoon

89212.0016

7891

26021 7590 05/08/2009
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,965	Applicant(s) HOON ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-13,15-18,20,21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-13,15-18,20,21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response to the office action filed on January 30, 2009 has been considered and acknowledged.

Status of the Application

2. Currently claims 1-2, 4-5, 7-13, 15-18, 20-21, and 23-24 are under examination. All arguments and amendment have been fully considered and thoroughly reviewed and deemed unpersuasive for the reasons that follow. This action is made FINAL.

Response to arguments:

3. With regard to the rejections of claims 1-2, 5, 7-13, 16-18, 20-21, and 23-24 under 35 USC 102(e) or 102(b) as being anticipated by Klein (US 6,673,541 and WO 00/17390), Applicants' arguments were fully considered and found unpersuasive. Applicants argue that Klein teaches the use of cellular DNA from bone marrow and does not anticipate the instant claims that require cell-free DNA from bone marrow sample. Applicants' arguments were found unpersuasive. First, the instant specification on page 11, line 15-28 discloses that the use of bone marrow aspirates comprising tumor cells as cell-free bone marrow sample. Second, the instant specification does not define cell-free bone marrow. Accordingly the cell-free DNA from bone marrow samples read on tumor DNA from bone marrow aspirates and Klein does teach use of DNA isolated from bone marrow aspirates. Second, the claims as presented broadly recite 'bone marrow sample from a subject' encompasses bone marrow aspirates with circulating tumor cells, it does not necessarily read on bone marrow plasma samples. Third, with regard to the arguments on DNA markers, Klein teaches determining loss of heterozygosity using chromosomal DNA, not cell as such as asserted by the applicants. Accordingly the rejections are maintained.

4. With regard to the rejection of claims 4 and 15 under 35 USC 103(a) as being unpatentable over Klein in view of Silva et al., Applicants' arguments were fully considered and found unpersuasive. Applicants argue that Klein does not teach cell free bone marrow and the combination of Silva et al. does not cure the deficiency of Klein. Applicants' also argue that Silva et al. teach acellular DNA from plasma samples and one skilled in the art would not have motivated to combine the teachings to derive at the instant invention. Applicants' arguments were found unpersuasive. First, as discussed above the instant specification does not define cell-free bone marrow and Klein teaches the use of bone marrow aspirate samples that meet said limitation. Second, Silva et al. reference is used to show the use of DNA markers as claimed in claims 4 and 15 and not on the acellular DNA as asserted by the Applicants. Third, with regard to attacking references individually, MPEP 2145 states One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Fourth, examiner notes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, specific motivation is provided in the rejection, which states that an ordinary person skilled in the art would have a reasonable expectation of success that the combination of the method of Klein et al. and the DNA markers of Silva et al. would result in a sensitive method for detecting cancer because Silva et al. explicitly taught the

use of microsatellite markers in detecting cancer and the association of said markers in the prognosis of cancer (see page 71, abstract). Accordingly the rejection is maintained.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637